IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

THE RESEARCH FOUNDATION OF STATE UNIVERSITY OF NEW YORK; NEW YORK UNIVERSITY; GALDERMA LABORATORIES, INC.; and GALDERMA LABORATORIES, L.P.;	**Public Version Released May 25, 2012**
Plaintiffs,	
v.	Civ. No. 09-184-LPS
MYLAN PHARMACEUTICALS INC.,	
Defendant.	
MYLAN PHARMACEUTICALS INC.,	
Plaintiff,	
v.	Civ. No. 10-892-LPS
GALDERMA LABORATORIES INC.; GALDERMA LABORATORIES, L.P.; and SUPERNUS PHARMACEUTICALS, INC.	**REDACTED**
Defendants.	

MEMORANDUM ORDER

I. BACKGROUND

The procedural history of this case is set forth in the Court's comprehensive post-trial opinion, which was issued on August 26, 2011. (D.I. 278)[1] In its opinion, the Court concluded

[1]Unless otherwise stated, all docket index citations are to Civil Action Number 09-184-LPS.

that all asserted claims of United States Patent No. 7,749,532 (the "Chang Patent")[2] were valid and infringed. (*Id.* at 62, 65-66)

Earlier, on June 28, 2010, the Court granted Galderma's[3] motion for a preliminary injunction based on, *inter alia*, its conclusion that Galderma was likely to succeed on the merits with respect to infringement and validity of the Ashley Patents. (D.I. 176; D.I. 177) However, in the post-trial opinion, the Court concluded that Galderma had failed to prove infringement of the Ashley Patents. (D.I. 278 at 39)

The Chang Patent was issued on July 6, 2010, during the pendency of the instant litigation, which had previously involved only allegations of infringement of the two Ashley Patents and the two Amin Patents. (D.I. 1) A party may bring suit on patents listed in the Orange Book after the filing date of an ANDA. *See Impax Labs., Inc. v. Aventis Pharms. Inc.*, 468 F.3d 1366, 1372-73 (Fed. Cir. 2006).

In entering the preliminary injunction, the Court required Galderma to post a $26 million bond, to be available in the event the preliminary injunction was ultimately determined to have been improvidently granted.

Given this unusual set of circumstances, after issuing its post-trial opinion the Court directed the parties to submit additional briefing regarding remedies. (D.I. 279) This supplemental briefing was completed on September 7, 2011. (D.I. 280; D.I. 283; D.I. 286; D.I. 287) The Court then heard argument on the matter of remedies on February 17, 2012. (D.I. 303)

---

[2]As noted in the Court's post-trial opinion, there are five patents-in-suit. In addition to the Chang Patent, Galderma also asserted U.S. Patent Nos. 7,211,267 and 7,232,572 (the "Ashley Patents") as well as U.S. Patent Nos. 5,789,395 and 5,919,775 (the "Amin Patents").

[3]The parties' names in this opinion are the same as those used in the Court's post-trial opinion.

(hereinafter "Tr.")

Galderma asks that the Court: "(1) order that the effective date of Mylan's ANDA 90-855 be a date which is not earlier than December 19, 2027, and (2) enjoin Mylan and those in concert with Mylan from the commercial manufacture, use, sale, offer for sale within the United States or importation into the United States of any drug product described in Mylan's ANDA 90-855 . . . until expiration of the Chang Patent." (D.I. 283 at 1) Galderma also opposes Mylan's effort to be compensated with the $26 million bond the Court required Galderma to post upon entry of the preliminary injunction, and further opposes Mylan's request that the Court deny Galderma's claim that this case should be deemed "exceptional."

Mylan requests "that the Court issue an Order: (1) denying a permanent injunction; (2) providing for determination of a reasonable royalty to be paid by Mylan to Galderma for future Mylan sales pending appeal; (3) awarding the entire $26 million bond to Mylan; (4) denying Galderma's request for relief under 35 U.S.C. §§ 271(e)(4)(A) and (B); and (5) entering judgment in Mylan's favor on all of Galderma's exceptional case claims." (D.I. 280 at 10)

For the reasons set forth below, the Court has decided to: (1) enter a permanent injunction, enjoining Mylan and those in concert with it from the commercial manufacture, use, sale, and offer for sale within the United States or importation into the United States of any drug product described in Mylan's ANDA 90-855 until expiration of the Chang Patent; (2) order that the effective date of Mylan's ANDA 90-855 be delayed to no earlier than December 19, 2027; (3) deny Mylan's request to recover some or all of the $26 million bond posted by Galderma in connection with the preliminary injunction; and (4) deny Galderma's claim that this case be

deemed "exceptional."

II. PERMANENT INJUNCTION

Galderma seeks a permanent injunction on two distinct statutory bases: 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283. Galderma insists that "Congress ***mandates*** that where infringement is found based on an ANDA copying a patented drug, the generic not be permitted to market prior to the patent's expiration. Any different result here would undermine the balance that Congress set forth in the Hatch-Waxman amendments." (D.I. 287 at 2) (citing *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367-68 (Fed. Cir. 2008)) Mylan contends that, instead of a permanent injunction, a reasonable royalty on future sales of their generic product would be more appropriate. "Under some circumstances, awarding an ongoing royalty for patent infringement in lieu of an injunction may be appropriate." *Paice LLC v. Toyota Motor Corp.*, 504 F.3d 1293, 1314 (Fed. Cir. 2007). "Mylan also requests the Court to order the parties to submit additional briefs and evidence regarding the appropriate royalty on Mylan's future sales." (D.I. 280 at 6)

The Court will grant a permanent injunction pursuant to 35 U.S.C. § 283. A patentee seeking permanent injunctive relief under Section 283 must demonstrate each of the following: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

As explained below, Galderma has met its burden with respect to each of the foregoing

elements.

A. Irreparable Injury

The Court has already addressed irreparable injury in its preliminary injunction opinion. (D.I. 177 at 28-32) Although the discussion there is in the context of the Ashley Patents, the same irreparable harms flow from infringement of the Chang Patent. No new or different evidence other than what was considered at the preliminary injunction stage appears in the record.

As Galderma summarizes, here "the patentee makes and sells the patented product, the market is limited, the parties are direct competitors, and no licenses have been given to others." (D.I. 283 at 8 n.6) In the absence of an injunction, Galderma will suffer an incalculable and non-compensable loss of market share, as well as price erosion and the potential loss of qualified employees and reduced research and development opportunities, all of which support a finding of irreparable harm. (*Id.* at 9; D.I. 288 ¶¶ 7-8) *See also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir. 2008); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001).

B. Adequacy of Monetary Damages

The Court has previously rejected Mylan's contention that Galderma's harm is calculable and can be compensated by monetary damages. (D.I. 177 at 32) The Court is not persuaded that the result should be any different under the present circumstances.

The remedies available to Galderma at law would not be adequate. Oracea®'s success and growth in the marketplace build Plaintiffs' goodwill. In the absence of an injunction, Galderma would lose the right to exclude others from the marketplace, which is an important

right that arises from patent protection. Moreover, the Court agrees with Galderma that given the significantly lower price of Mylan's anticipated generic product,[4] any royalties on Mylan's sales would likely be inadequate to compensate Galderma for losses caused by Mylan's market entry.

C. Balance of Hardships

In connection with the preliminary injunction motion, the Court found that the balance of hardships favored Galderma. (*Id.* at 37) Although new factors must now be considered, the Court reaches the same conclusion again.

Mylan argues that in now assessing the balance of hardships, the Court should consider that "Galderma has already profited from an immeasurable benefit to which it was not entitled" by the entry of the preliminary injunction. (D.I. 280 at 5) According to Mylan, "[t]hat huge, yet undeserved, benefit outweighs any alleged harm that Galderma would suffer in the absence of a permanent injunction arising from infringement of the Chang patent." (*Id.*) "[T]he preliminary injunction (based on patents that Mylan was found not to infringe) shielded Galderma from legitimate business competition from Mylan . . . ." (D.I. 286 at 1)

However, the Court agrees with Galderma that, to the extent Mylan has been "harmed" by the Court's entry of a preliminary injunction, that harm is largely "of Mylan's own making," as "Mylan chose not to present its winning '*in vivo*' argument at the preliminary injunction hearing." (D.I. 287 at 4 n.3) *See generally Novartis Consumer Health, Inc. v. Johnson & Johnson–Merck Consumer Pharms. Co.*, 290 F.3d 578, 596 (3d Cir. 2002) ("[T]he injury a defendant might suffer if an injunction were imposed may be discounted by the fact that the

---

[4]For example, [redacted] (D.I. 282 ¶ 9)

defendant brought that injury upon itself.").

Thus, the Court concludes that Galderma has met its burden to show that the balance of hardships favors entry of a permanent injunction.

D. Public Interest

For the same reasons that the Court cited in connection with the preliminary injunction (D.I. 177 at 37-38), the Court concludes that the public interest favors entry of a permanent injunction. Mylan's product infringes a valid patent. Consistent with the careful balancing of competing interests embodied in the Hatch-Waxman scheme, the public interest favors strict enforcement of Galderma's patent rights, even at the cost of generic competition for Galderma's Oracea® product.

E. Scope of Injunction

The Court will permanently enjoin Mylan and those in concert with it from the commercial manufacture, use, sale, and offer for sale within the United States or importation into the United States of any drug product described in Mylan's ANDA 90-855, until expiration of the Chang Patent.[5]

III. Effective Date of FDA Approval Under 35 U.S.C. § 271(e)(4)(A)

Galderma asserts that it "is ***entitled*** by statute to a change in the effective date of Mylan's ANDA to no earlier than December 19, 2027," because 35 U.S.C. § 271(e)(4)(A) states that a district court "***shall***" order such relief upon finding that a patent has been infringed under 35

[5]It is not necessary to resolve the parties' dispute as to whether Galderma is also entitled to an injunction pursuant to Section 271(e)(4)(B), as such relief would be redundant of the relief granted under Section 283.

U.S.C. § 271(e)(2). (D.I. 287 at 1) (emphasis added).[6]

Mylan responds that Galderma is not entitled to an order delaying FDA approval of Mylan's ANDA product. According to Mylan, two procedural defects bar Galderma's request for relief under Section 271(e)(4)(A). First, Mylan argues, Section 271(e)(4)(A) applies only in actions brought pursuant to Section 271(e)(2), yet here the "parties' claims and defenses regarding the Chang patent do not arise under Section 271(e)(2)," as the parties' pleadings were directed instead to Sections 271(a), (b), and/or (c). (D.I. 280 at 9; D.I. 286 at 4) Second, Mylan asserts that "[e]ven if Galderma had requested relief under Section 271(e)(2), . . . a Paragraph IV certification for the Chang patent is a necessary predicate to a claim under Section 271(e)." (D.I. 286 at 4)

The Court agrees with Galderma that neither of these purported procedural defects bars Plaintiffs' request for relief under Section 271(e)(4)(A). Although the parties' pleadings do not appear explicitly to invoke Section 271(e)(2) in connection with the Chang Patent, the subsequent Joint Pretrial Order clarifies that Mylan's declaratory judgment action against the Chang Patent was brought pursuant to Section 271(e) of the Hatch-Waxman Act. (D.I. 128 (C.A. No. 10-892) at 5, ¶ 11) ("This is an action . . . brought pursuant to the Hatch-Waxman Act . . . and 35 U.S.C. § 271(e).") Because the parties' Pretrial Order superseded their prior pleadings and controlled the subsequent course of action, *see* Fed. R. Civ. P. 16(d), Galderma's assertion of

---

[6]In pertinent part, 35 U.S.C. § 271(e)(2)(A) provides: "It shall be an act of infringement to submit – an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act . . . for a drug claimed in a patent or the use of which is claimed in a patent." In turn, 35 U.S.C. § 271(e)(4)(A) states: "For an act of infringement described in paragraph (2) – the court shall order the effective date of any approval of the drug . . . to be a date which is not earlier than the date of the expiration of the patent which has been infringed."

the Chang Patent against Mylan did sufficiently arise under Section 271(e)(2). *See Rockwell Int'l Corp. v. U.S.*, 549 U.S. 457, 474 (2007) .

The Court further concludes that a Paragraph IV certification against the Chang Patent was not required for Galderma to bring suit under Section 271(e)(2). The Federal Circuit recently addressed a similar issue in *AstraZeneca Pharmaceuticals LP v. Apotex Corp.*, 669 F.3d 1370 (Fed. Cir. 2012) ("*AstraZeneca*"). There, the Federal Circuit held that a Paragraph IV certification was not required for subject matter jurisdiction over a patentee's Section 271(e)(2) claims. *Id.* at 1377 ("[T]he requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2)."). The Federal Circuit further stated that "[w]hen considering allegations that an ANDA filing infringes a patented method, § 271(e)(2) directs [the] analysis to the scope of approval sought in the ANDA." *Id.* at 1379. In *AstraZeneca*, the plaintiffs failed to state a viable claim under Section 271(e)(2) because the defendant generic manufacturers were not seeking FDA approval for the patented methods for which they had not filed Paragraph IV certifications; instead, the defendants had affirmatively excluded those patented indications from their ANDAs. *Id.* at 1379-80. Here, by contrast, Mylan, by initiating its declaratory judgment action – seeking a declaration that its ANDA product would not infringe the Chang Patent and/or that the Chang Patent is invalid – affirmatively indicated its intent to seek FDA approval for at least the methods claimed in the Chang Patent.[7]

In sum, because Galderma properly invoked the Court's subject matter jurisdiction, stated

---

[7]Prior to trial, Mylan conceded infringement of Claims 1-3, 5, 7-9, 13-17, and 19-21 of the Chang Patent, and disputed infringement only with respect to Claims 4 and 18. (D.I. 278 at 62) Claims 15-19 of the Chang Patent are method of treatment claims.

a claim pursuant to Section 271(e)(2), and ultimately prevailed on the merits at trial, the Court will grant Galderma's request for relief under Section 271(e)(4)(A).

IV. DISPOSITION OF BOND

The Court entered its preliminary injunction order on June 28, 2010. The FDA approved Mylan's ANDA product on July 1, 2010. The Chang Patent issued on July 6, 2010. Thus, between July 1 and 6, 2010, the only legal impediment to Mylan's launch of its ANDA product was this Court's preliminary injunction order.

At the time the Court entered its preliminary injunction order, it required Galderma to post an injunction bond of $26 million. The Court required Galderma to do so within 10 calendar days of receiving written notice from Mylan of FDA final approval of Mylan's ANDA 90-855. (D.I. 177 at 40) Galderma timely posted its bond on July 8, 2010. (D.I. 193)

Mylan contends that, absent the Court's preliminary injunction order, it would have launched its generic product on July 1, 2010 and would have kept selling it until issuance of the Chang Patent on July 6, 2010. Mylan insists, thus, that it was kept off the market during that interval only as a result of what the Court eventually determined was an improvidently granted preliminary injunction. As compensation, Mylan seeks "to recover the damages it suffered during the pendency of the preliminary injunction," damages which Mylan asserts [redacted] (D.I. 280 at 1)[8]

Specifically, Mylan contends that [redacted]

[8]Given the Court's ruling, it is unnecessary to provide Galderma discovery into whether Mylan would actually have launched its product on July 1, 2010. (*See* D.I. 287 at 5)

[redacted] (D.I. 282 ¶ 4) Mylan further contends that [redacted] (*Id.* ¶ 5) Mylan goes on to argue that [redacted] (*Id.* ¶¶ 6, 9)

According to Mylan, "[t]he bond required by Rule 65(c) is intended to cover at least the 'payment of such costs and damages as may be incurred or suffered by any party who is found to have been wrongfully enjoined.'" (D.I. 280 at 7) (citing *Virginia Plastics Co. v. Biostim Inc.*, 820 F.2d 76, 77 n.1 (3d Cir. 1987)) The bond may "provide[] a fund to use to compensate incorrectly enjoined defendants." *Instant Air Freight Co. v. C.F. Air Freight, Inc.*, 882 F.2d 797, 804 (3d Cir. 1989). Mylan argues "'there is a rebuttable presumption that a wrongfully enjoined party is entitled to have the security executed so as to recover provable damages.'" (*Id.* at 9) (quoting *Global Naps, Inc. v. Verizon New England, Inc.*, 489 F.3d 13, 23 (1st Cir. 2007)).

The Court denies Mylan's request. As an initial matter, the record is not entirely clear that Mylan would, in fact, have launched its ANDA product on July 1, 2010, particularly given the ongoing nature of the instant litigation and Mylan's knowledge that [redacted] (*See* D.I. 287 at 4, Ex. H; D.I. 241 at 9:25-10:1) As the first-filer, Mylan knew that

[9]Galderma argued at the preliminary injunction stage that Mylan could launch as soon as it received FDA approval for its ANDA, but now contends that Mylan could or would ***not*** have launched on July 1, 2010, in the absence of the preliminary injunction. Mylan suggests that judicial estoppel bars Galderma from advocating its present position. The Court is not persuaded. Judicial estoppel is an "extreme remedy" that should only be applied where a party

its opportunity to enjoy the full 180 days of generic exclusivity could be cut short at any point, either by order of this Court or issuance of the Chang Patent. The Court is not convinced that, under these circumstances, Mylan would have launched its product immediately upon receiving FDA approval on July 1, 2010, particularly in view of the evidence identified by Galderma indicating that [redacted] (D.I. 287, Exs. F and G)

Even assuming Mylan could ultimately prove that it would have launched on July 1 and [redacted] to some extent the harm Mylan suffered from entry of the preliminary injunction was its own fault. As explained above in connection with the permanent injunction analysis, Mylan's "winning" argument with respect to the non-infringement of the Ashley Patents – based on *in vivo* data, as opposed to *in vitro* data – was not presented to the Court until trial. (D.I. 278 at 45)

Additionally, while the harm to Mylan occurred from July 1 to 6, 2010, Galderma's bond was not posted until July 8, 2010. There is authority for the proposition that a party may only recover on a bond for harms that occurred during the pendency of the bond (as opposed to during the pendency of just the injunction). *See Glaxo Group Ltd. v. Leavitt*, 481 F. Supp. 2d 434, 437 (D. Md. 2007) (stating harm underlying claim for bond on preliminary injunction "must have

---

has taken "irreconcilably inconsistent" positions in "bad faith," tantamount to a knowing misrepresentation or fraud on the court. *Chao v. Roy's Constr., Inc.*, 517 F.3d 180, 186 (3d Cir. 2008); *Krystal Cadillac-Oldsmobile GMC Truck, Inc. v. Gen. Motors Corp.*, 337 F.3d 314, 319 (3d Cir. 2003). Galderma's positions are not irreconcilably inconsistent, since there is record evidence, created and discovered ***after*** the preliminary injunction hearing, suggesting that [redacted] (*See* D.I. 287, Exs. F and G) Nor does the record suggest that Galderma adopted its positions in bad faith. Counsel for Galderma represented at the hearing that Galderma sought a preliminary injunction, in part, because Mylan refused to disclose whether or not it intended to launch upon receiving FDA approval, prompting legitimate concerns at that time that Mylan might enter the market absent an injunction. (Tr. at 83)

been suffered during the period in which the bond was in effect"); Wright & Miller, 11A Fed. Prac. & Proc. Civ. § 2973 (2d ed.) ("Another significant limitation on the ability to recover on the bond is that the damages claimed must have been suffered during the period in which the bond was in effect.").

Consequently, the Court denies Mylan's request to recover all or a portion of the preliminary injunction bond posted by Galderma.

V. EXCEPTIONAL CASE

Galderma alleges that this is an "exceptional case," pursuant to 35 U.S.C. § 285. Mylan asks that the Court enter judgment on Galderma's exceptional case allegations in its favor as "those claims are mooted" by the Court's post-trial opinion. (D.I. 280 at 2) The Court agrees with Mylan, as Mylan succesfully prevailed on the issue of infringement with respect to the Ashley and Amin Patents, as well as the invalidity of the Amin Patents.

VI. CONCLUSION

At Wilmington, this 16th day of May, 2012:

WHEREAS, the Court held a four-day bench trial in these actions from July 5, 2011 to July 8, 2011; and

WHEREAS, the Court issued an opinion on August 26, 2011, setting forth its Findings of Fact and Conclusions of Law; and

WHEREAS, the Court has considered the briefs submitted by the parties pursuant to the Court's August 26, 2011 Order for supplemental briefing addressing the appropriate remedy in view of the Court's opinion, as well as the arguments made at the February 17, 2012 hearing:

IT IS HEREBY ORDERED THAT:

1. Claims 1, 2, 3, 4, 5, 7, 8, 9, 13, 14, 15, 16, 17, 18, 19, 20, and 21 of U.S. Patent No. 7,749,532 ("the '532 patent") are infringed by Mylan's ANDA No. 90-855 and are not invalid;

2. Claims 1, 22, 23, 26, 28, and 30 of U.S. Patent No. 7,211,267 ("the '267 patent") and Claims 1, 12, 13, 14, 15, 20, 21, 23, 24, and 26 of U.S. Patent No. 7, 232,572 ("the '572 patent") are not infringed and are not invalid;

3. Claims 1, 2, 4, 11, 13, 14, and 16 of U.S. Patent No. 5,789,395 ("the '395 patent") and Claims 1, 2, 4, 5, and 9 of U.S. Patent No. 5,919,775 ("the '775 patent") are not infringed and are invalid for anticipation;

4. Pursuant to 35 U.S.C. § 271(e)(4)(A), the Food and Drug Administration ("FDA") is directed to withdraw final approval of any product that is the subject of Mylan's Abbreviated New Drug Application ("ANDA") No. 90-855, and the effective date of any approval of Mylan's ANDA No. 90-855 shall be a date which is not earlier than December 19, 2027, the expiration date of the '532 patent, or any extension of that date;

5. Pursuant to 35 U.S.C. § 283, Mylan and its officers, agents, servants, employees, and attorneys, and any and all other persons who are in active concert or participation with any of them, are hereby enjoined until the expiration of the '532 patent from making, using, offering for sale, or selling within the United States, or importing into the United States, any product that is the subject of Mylan's ANDA No. 90-855; and

6. Pursuant to 35 U.S.C. § 285, this case is deemed not exceptional.

IT IS FURTHER ORDERED THAT the Clerk is directed to CLOSE this case.

UNITED STATES DISTRICT JUDGE